

Templates and core content for the patient information leaflet and patient-held monitoring and dosage record

These documents can support NHS organisations and professionals in the safer management and administration of oral methotrexate. The templates contain the core content that should be in the patient information leaflet and the patient-held monitoring and dosage record. The documents can have information added for local preferences, style and approach. However, none of the core content should be removed. You may want to consider producing them in conjunction with other NHS organisations in your area and putting the information on your website.

All the information reflects what patients and professionals have told the NPSA they need to support them at the outset and during the course of treatment.

General points, which apply to both the patient information leaflet and the patient-held monitoring and dosage record, are below. More detailed information for each of the two documents is provided in the following pages.

Content presentation guidelines

- Use a font that is easy to read such as Ariel or Frutiger
- The font size should be 14 point for headings and 12 point for text
- There should be a 1½ line spacing
- Headings should be in bold and text in plain
- Headings will stand out more if they are in a different colour to the rest of the text

Layout and design

You can download PDF files of the recommended content on the NPSA website at www.npsa.nhs.uk/advice and this includes a Welsh translation of the patient information leaflet.

Testing and evaluation with patients and clinicians has shown that it is most effective to produce:

- the patient information leaflet as an A4 (297x210mm) four-page document
- the patient-held monitoring and dosage record as an A6 (149x105mm) booklet with multiple pages of the monitoring tables and pages for recording dosage regimes. These are shown on the following pages.

Notice for clinicians

The release date of the information leaflet and patient-held monitoring and dosage record is 29 July 2004. Clinicians should ensure that they take into account any relevant developments in clinician practice and knowledge since the release date.

In the event that a clinician has any comments or feedback about this patient-held monitoring and dosage record, they should contact Wendy Harris of the National Patient Safety Agency at wendy.harris@npsa.nhs.uk

Methotrexate

What it is

Methotrexate is a well-established, effective treatment for several different types of rheumatic disease (rheumatoid arthritis and psoriatic arthritis) and severe psoriasis. It may also be used for other conditions.

What it can do

It can reduce inflammation (swelling) so that joints do not stiffen or skin thicken as much. It is not a painkiller.

Seeing the benefits

It may be 3 to 12 weeks before you notice any benefits - but it is working during this period. Rheumatoid arthritis and psoriasis are chronic conditions and methotrexate may need to be taken for several years.

Your dose

Once a week

Your tablets should be taken once a week on the same day each week.

How to take methotrexate

You should take the tablets by mouth, one hour after food in the evening. Take the tablets with a glass of water while you are sitting or standing. Swallow the tablets whole and do not crush or chew them.

Take care

Handle the tablets as little as possible. Store them at room temperature and out of children's reach.

Depending upon how well the tablets work for you, the dose you need to take may change. If your dose changes, the number of tablets you should take may change. But you will still only need to take them once a week.

Methotrexate is made in two different strengths, 2.5mg and 10mg. The two strengths are different shapes but are a very similar colour, so always check you have been given the right strength by your doctor or pharmacist.

Do not take the tablets if you think you have the wrong strength. Check with your doctor or pharmacist as soon as possible.

If you are sick

If you are sick within a few hours of taking methotrexate tell your GP. You may be told to take another dose or to wait until the next dose is due the following week.

Patients who are regularly sick after every dose may be given methotrexate by injection instead.

The key to preventing dosing errors with methotrexate is stressing the weekly dosing regime: some patients have assumed that their doctor or nurse had made a mistake and have taken the dose each day.

Although patients are told when to attend for tests, some do not because they do not understand either why they should or the importance of the tests, placing themselves at risk of possible toxicity.

All drugs affect people differently in that not all will experience the same type of or intensity of side effects. However, there have been fatal incidents when, for example, neither the patient nor their clinician has made the link between methotrexate and breathlessness.

Why you need regular blood tests

It is important that you do not miss your blood test. You must not take methotrexate unless you are having regular blood tests every 4 to 12 weeks. They tell your doctor how well methotrexate is working.

Methotrexate reduces the production of blood cells and this can make you more vulnerable to infections. Blood tests will show if you are developing any side effects. If your blood, liver, kidneys or lungs are being affected, your treatment will be changed or stopped immediately.

Avoid having blood tests done directly after taking your dose as this can mask any changes.

When you start taking methotrexate, your doctor will give you a booklet in which the results of your blood tests must be recorded. This will help you, your doctor and pharmacist know that the dose is right for you and not adversely affecting your body. Your doctor may increase or decrease the number of tablets you take at each dose depending upon the results of your tests.

Possible side effects

Most people do well on methotrexate but it can affect your immune system and make you more vulnerable to illness. Occasionally, it can also produce side effects, some immediately and some within a few weeks.

Immediate side effects (within 48 hours)

Tell your doctor if these symptoms persist or occur after every dose:

- sickness
- diarrhoea
- skin rashes

Delayed side effects (within 2 to 3 weeks)

- mouth ulcers
- hair loss

Long term side effects (these side effects are rare)

- inflammation of the lung - if you become breathless, tell your doctor immediately
- bone marrow damage - your regular blood count test will check how well your bone marrow is working. Possible indicators of bone marrow damage are anaemia, regularly catching infections, and bruising and bleeding easily

The patient information leaflet in your tablet packet has a more detailed list of possible side effects.

Some doctors also prescribe folic acid tablets as these can reduce the likelihood of side effects.

Things to tell your doctor immediately

If you have any of the following, tell your doctor immediately:

- infections including fever, chills or sore throats
- unexplained skin rash, ulcerations or soreness of skin
- yellowing of the skin or generalised itching
- bleeding gums, black tarry stools or unexpected bleeding or bruising
- chest pain, difficulty breathing or a dry, persistent cough
- sore mouth or mouth ulcers
- severe and continuing diarrhoea, vomiting or stomach pains
- vaginal inflammation or ulcers

See your doctor if you develop any new symptoms after starting methotrexate.

Chicken pox and shingles

If you are taking methotrexate and you develop chicken pox or shingles and it seems to be severe, you should see your doctor as you may need special treatment.

Other advice**Taking other medicines**

Always check with your doctor or pharmacist before taking any other medicine. This includes medicines you can buy at a garage, newsagent, supermarket or chemist such as aspirin, paracetamol, other painkillers and medicines for coughs, colds and flu. This equally applies to herbal and alternative remedies. These can react with methotrexate and affect your treatment.

Also, the symptoms you are trying to treat may be a sign of methotrexate not working safely for you. It is important for your doctor or pharmacist to know so they can help you. Keep a record of any symptoms and discuss them with your doctor.

Drinking alcohol

Alcohol can react with methotrexate so it is advisable not to drink. However, an occasional drink may not be expected to cause significant side effects. Your doctor can give you more information and advice about this.

Food

Food made from unpasteurised milk, such as soft cheese and uncooked meats such as pate, may be a source of bacteria which could increase your risk of infection. Read food labels carefully, and avoid eating these types of food.

To help patients safely use methotrexate, it is important that they are aware of any important information.

Having a baby

Methotrexate can reduce fertility in men and women. It can also damage an unborn child.

Women

Do not take methotrexate if you are pregnant or breastfeeding. It is recommended that you wait six months after finishing your treatment, before trying to become pregnant. You should talk to your doctor or nurse about effective contraception.

Men

It is recommended that you wait six months after finishing your treatment, before trying to father a child as your sperm can be affected. You should use effective contraception; talk to your doctor or nurse if you need advice.

Vaccinations

Your doctor or nurse should not offer you any immunisation injections that have any of the live vaccines such as polio and rubella (German measles). However, flu vaccines are safe.

Other information

If your treatment ends and you have some tablets left over, return them to your pharmacist. Do not flush them down the toilet or throw them away.

When you were given this leaflet, you should also have received a booklet for recording your blood test results. If you did not receive one, ask your hospital clinic for a copy.

Contact information

NHS Direct	Tel: 0845 4647 www.nhsdirect.nhs.uk
NHS Direct Wales	Tel: 0845 4647 www.nhsdirect.wales.nhs.uk
Arthritis Care	Tel : 020 7380 6500 www.arthritiscare.org.uk

Important notice

This patient information leaflet has been compiled after consideration of the information available by the National Patient Safety Agency as at July 2004. It is not intended to be exhaustive and should not be used as a substitute for consulting your clinician on any particular issue. The National Patient Safety Agency makes no representations, warranties or guarantees as to the accuracy, completeness or adequacy of any of the content of this patient information leaflet and cannot be held responsible for any liability, loss or damage whatsoever which may arise from the use of, or reliance upon, this patient information leaflet, except as may otherwise be required by law.